4160-01-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2012-N-0002]

Oral Dosage Form New Animal Drugs; Change of Sponsor; Lincomycin Hydrochloride Soluble

Powder; Penicillin G Potassium in Drinking Water; Tetracycline Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for three abbreviated new animal drug applications (ANADAs) for lincomycin hydrochloride; penicillin G potassium, USP; and tetracycline hydrochloride soluble powders administered in drinking water from Teva Animal Health, Inc., to Quo Vademus, LLC.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

#### FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Teva Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-136 for Tetracycline Hydrochloride Soluble Powder 324; ANADA 200-303 for Lincomycin Hydrochloride Soluble Powder; and ANADA 200-347 for Penicillin G Potassium, USP, all soluble powders administered in drinking water to Quo Vademus, LLC, 277 Faison West McGowan Rd., Kenansville, NC 28349. Accordingly, the Agency is amending the regulations in part 520 (21 CFR part 520) to reflect the transfer of ownership and a current format.

In addition FDA has noticed two errors in § 520.1696 Penicillin oral dosage forms. At this time, § 520.1696a is being removed because no sponsor is listed, and an obsolete drug labeler code is being removed from § 520.1696d. These actions are being taken to improve the accuracy of the regulations.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

### List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

#### PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

- 2. In § 520.1263, revise the section heading to read as follows:
- § 520.1263 Lincomycin.

\* \* \* \* \*

- 3. In § 520.1263c, revise the section heading and paragraph (b) to read as follows:
- § 520.1263c Lincomycin powder.

\* \* \* \* \*

(b) <u>Sponsors</u>. See Nos. 000009, 046573, 054925, 061623, and 076475 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

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- 4. In § 520.1696, revise the section heading to read as follows:
- § 520.1696 Penicillin.

\* \* \* \* \*

- § 520.1696a [Removed and Reserved]
  - 5. Remove and reserve § 520.1696a.
- 6. In § 520.1696b, revise the section heading, paragraphs (a) and (b), and the heading for paragraph (c) to read as follows:
- § 520.1696b Penicillin G powder.
- (a) <u>Specifications</u>. Each gram of powder contains penicillin G potassium equivalent to 1.54 million units of penicillin G.
- (b) <u>Sponsors</u>. See Nos. 010515, 046573, 053501, 059320, 061623 and 076475 in § 510.600(c) of this chapter.
  - (c) Conditions of use in turkeys—

\* \* \* \* \*

7. In § 520.1696c, revise the section heading and remove and reserve paragraph (c) to read as follows:

# § 520.1696c Penicillin V powder.

\* \* \* \* \*

8. In § 520.1696d, revise the section heading and paragraph (b) and remove and reserve paragraph (c) to read as follows:

## § 520.1696d Penicillin V tablets.

\* \* \* \* \*

(b) Sponsors. See Nos. 050604 and 053501 in § 510.600(c) of this chapter.

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- 9. In § 520.2345, revise the section heading to read as follows:
- § 520.2345 Tetracycline.

\* \* \* \* \*

10. In § 520.2345d, revise paragraph (b)(4) to read as follows:

## § 520.2345d Tetracycline powder.

\* \* \* \* \*

- (b) \* \* \*
- (4) Nos. 054925, 057561, 061623, and 076475: 324 grams per pound as in paragraph (d) of this section.

\* \* \* \* \*

Dated: March 27, 2012.

William T. Flynn,

Acting Director,

Center for Veterinary Medicine.

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